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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,342	01/26/2001	Mark G. Fleischhacker	058442/9191	6291

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/770,342	Applicant(s) FLEISCHHACKER, MARK G.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05122004</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This Office Action is responsive to the Amendment filed May 27, 2004. The Examiner acknowledges that no changes to the claims are made in said Amendment. Claims 1-21 are pending.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-12, 16, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne ('640). Osborne teaches a composite guide wire shaft. Osborne teaches several embodiments for the composite guide wire shaft. *With the exception of the "hybrid" embodiment disclosed at column 5, lines 35-54*, the guide wires include a core wire that has proximal, medial and distal segments where the core wire is formed of a non-metallic, non-woven material. The core wire may be formed of a plurality of fibers chosen from a group consisting of boron fibers, carbon fibers, fiberglass, polymeric aromatic nylon fibers, silicon carbide filaments, or the like (column 4, lines 7-11). The fibers are bonded to one another by being embedded in an adhesive matrix such that the tiny spaces between the wires are substantially filled with the adhesive (column 2, lines 44-47). The adhesive matrices can be formed of a variety of binder resins, such as epoxy resins, polyester resins, vinyl ester resin-type

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glues, and cyanoacrylates (column 4, lines 15-24). The core wire may be formed entirely of polymeric materials. The core wire may also be provided with an outer sleeve formed of polyethylene, Teflon ®, nylon or other suitable shrinkable material that may be provided with a hydrophilic outer coating (column 5, lines 7-20). The core wire may have proximal, medial and distal segments that have the same diameters (Figure 1) or distally tapered segments (Figure 2) that have increasing flexibility. As disclosed at column 5, lines 21-34, the core wire may include multiple, short non-metallic fibers that are "mixed" into the binder matrix. The term "mixed" implies that the fibers are randomly-disposed within the matrix and that the binder resin fills any void space between the fibers. The core wire may be provided with a helical coil on an outer surface of its distal end (column 5, lines 51-52).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Sirhan et al. ('875). Osborne, as discussed hereinabove, teaches all of the limitations of the claims except that the core wire comprises polyetheretherketone. Sirhan et al. teach that polyetheretherketone is known to be a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one

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having ordinary skill in the art at the time applicant's invention was made to use polyetheretherketone to make a core wire similar to that of Osborne in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters to form the fibers.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Nobuhiko ('263). Osborne, as discussed hereinabove, teaches all of the limitations of the claim except that the core wire is coated with PEBAX polyetherimide. Nobuhiko teaches coating a guidewire core 1 with PEBAX polyetherimide 2 to provide the guidewire with prolonged lubricating ability. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use PEBAX polyetherimide to coat a core wire similar to that of Osborne in view of the teachings of Nobuhiko in order to provide the guidewire with prolonged lubricating ability.

7. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Sirhan et al. ('875), and further in view of Moutafis et al. ('620).

Osborne, as discussed hereinabove, teaches a guidewire having a core wire formed of polymeric materials that is substantially completely covered with a second polymeric material. Osborne teaches all of the limitations of the claims except that polyetheretherketone and polyetherimide are used as the polymeric materials for construction.

Sirhan et al. teach that polyetheretherketone is known as a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would

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have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use a polyetheretherketone to make a core wire similar to that of Osborne in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters.

Osborne, as modified by Sirhan et al., teach all of the limitations of the claims except that the core wire is coated with polyetherimide. Moutafis et al. teach a plastic coated medical guidewire where a core wire is coated by a polyetherimide sleeve 14 (col. 3, lines 61-65) which is further coated with a hydrophilic lubricous coating 20 (col. 4, line 33). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to coat a polyetheretherketone a core wire similar to that of Osborne as modified by Sirhan et al., with a polyetherimide jacket and a lubricous coating in view of the teachings of Moutafis et al. as a design choice, merely selecting conventional polymeric materials to construct a guidewire that are known to provide a guidewire with steerability, flexibility, resistance to kinking and stiffness, and lubricity.

### ***Response to Arguments***

8. Applicant's arguments filed May 27, 2004 have been fully considered but they are not persuasive.

Regarding claims 19 and 20, Applicant contends that Osborne discloses a plurality of parallel, longitudinally oriented core fibers, and does not anticipate claims directed to randomly-disposed core fibers as described in the present invention. This argument is not persuasive. At column 5, lines 20-29, an embodiment of the Osborne core wire is described where the adhesive

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material used to bond the longitudinally-oriented fibers and helically oriented fibers is "*mixed* with short chopped fibers to give it added strength." The word "mixed" is defined as "blended together into one unit or mass" The American Heritage Dictionary® of the English Language (1992). The Examiner contends that by mixing or blending the short chopped fibers into the adhesive material the short chopped fibers will inherently become randomly-disposed in the adhesive material as one skilled in the art will realize that the orientation of the short chopped fibers cannot be controlled in such a manufacturing procedure. Furthermore, claims 19-21 use the transitional phrase "comprising" to define the claim. The transitional phrase "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03. Therefore, the core wire of Osborne having a plurality of short chopped fibers randomly disposed in the adhesive matrix anticipates claims 19-21 of the present invention even though the core wire of Osborne also includes a plurality of longitudinally-oriented fibers and helically oriented fibers.

Further regarding claims 19 and 20, Applicant contends the claims have been rejected over this reference early in the prosecution of the same application and that no new analysis or re-interpretation of Osborne '640 is included in the 11/24/2003 Office Action. This argument is not persuasive, as Applicant amended claim 19 in response to the original rejection presented in the Office Action of 5/23/2002 to require that the multiple non-metallic fibers be "randomly-disposed" rather than "helically-oriented" as originally presented. The new analysis or re-interpretation of Osborne '640 in response to the amended claims was presented in the 11/24/2003 Office Action and is reiterated hereinabove.

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With regard to Applicant's argument that the rejections of claims 1-12, 16, 17 and 21 appear to be inconsistent with the Manual of Patent Examining Procedure, this argument is not persuasive. While the aforementioned claims were not rejected as anticipated by the Osborne patent in the 5/23/2002 Office Action, the Examiner previously relied on the Cordis Corporation reference in the 5/23/2002 and 3/6/2003 Office Actions to provide the anticipatory teaching relating to these claims. When Applicant provided a Declaration under 37 C.F.R. 1.131 on September 11, 2003 eliminating the Cordis Corporation reference as valid prior art in the present application, the Examiner cited Osborne as an anticipatory reference with respect to the aforementioned claims after a re-interpretation and further analysis of the Osborne patent. The Examiner respectfully contends that irregardless of whether or not the rejections were articulated at time of the earliest Office Action in the prosecution process, the Osborne patent reads on all of the limitations of the claims of the present application as discussed herein.

Applicant further contends that Osborne teaches a core wire that is metallic in the paragraph beginning at column 5, line 34, and therefore does not anticipate the non-metallic requirement of the claims of the present application. This argument is not persuasive. The Examiner has been aware of this paragraph as is noted in the rejections set forth in the 11/24/2003 Office Action and reiterated hereinabove. This paragraph of the disclosure of Osborne is directed to only one alternative "hybrid" embodiment of the core wire. All of the other embodiments of the core wire disclosed by Osborne, and particularly the primary embodiment, appear to be entirely non-metallic.

Applicant further contends that Osborne clearly does not recognize the problems solved by the present invention relating to antenna effect and magnetic field deflection. This argument



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fail to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant further contends that "Osborne discusses at length the 'composite wire guide' which is their alleged invention," and that "a 'wire guide' clearly suggests to one skilled in the art the presence of metallic structures" while providing a definition of the word "wire" in an effort to support Applicant's position. This argument is not persuasive. The term "wire guide" would be synonymous to one of ordinary skill in the art with the term "guide wire" such as used in the present application as defined at page 3, lines 14-23 of the present application. Furthermore, it is unclear how Applicant can attempt to rely on the use of the word "wire" to indicate that the apparatus of Osborne is at least in part metallic, when Applicant repeatedly uses the word "wire" in the claims of the present application to define the non-metallic apparatus of the present invention. Applicant's disclosure has not provided a special definition for the word "wire" which would afford the present application a definition of the word "wire" that is any different from the word "wire" as used in the Osborne patent.

Finally with respect to the Osborne patent, Applicant contends that Osborne clearly and unambiguously discloses a guidewire which is "woven" while all pending claims of the present application require the guidewire to be "non-woven." This argument is not persuasive. The word "woven" is defined by The American Heritage Dictionary® of the English Language (1992) to mean constructed by interlacing or interweaving strands of material or made by winding in and out. The helically wound fibers of the Osborne patent are formed by winding first fibers in one direction around an axis and then cross-winding second fibers over top of the

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first fibers in an opposite direction (see Figure 1 and column 3, lines 42-46 and 56-65). At no time does the Osborne patent teach that the helically oriented fibers are *interlaced* or *wound in and out* with respect to each other. Therefore, the wire guide of Osborne is "non-woven."

With regard to the various dependent claims that were rejected by Osborne in conjunction with various secondary references, Applicant failed to provide specific arguments with respect to those rejections, instead relying on the arguments presented with regard to the Osborne patent to obviate those rejections. As discussed hereinabove, Applicant's arguments with respect to the Osborne patent are not persuasive. Therefore, the rejections of claims 1-21 as set forth in the 11/24/2003 Office Action are maintained.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

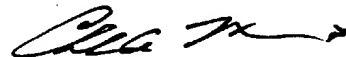
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

cam  
September 2, 2004